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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,995	03/27/2000	Satoru Nishimura	0213-1431-0	4205

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EXAMINER

EPPS, JANET L

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 12/05/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/534,995

Applicant(s)

NISHIMURA ET AL.

Examiner

Janet L. Epps

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1,7 and 19-22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 and 9 is/are allowed.
- 6) ☒ Claim(s) 2,4-6,8,10-12 and 14-18 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 2-6, 8-17 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that if the examination of an entire application can be made without serious burden, the examiner must examine it on its merits, and further that if claims directed to a product are found allowable, restricted process claims can be rejoined to the elected invention. This is not found persuasive because, the product claims have not been found allowable, and furthermore the examiner has demonstrated the inventions of Groups I-III are patentably distinct categories of invention by virtue of their separate classification. For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02.

The requirement is still deemed proper and is therefore made FINAL.

2. Claim 1, 7, and 18-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 4-6, 8-12, and 14-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are directed to genes that encode proteins having a sequence according to SEQ ID NO: 2, 4, 6, or 17, and proteins according to SEQ ID NO: 2, 4, 6, or 17 having deletions, substitutions, or additions of one or more amino acids and maintains choline monooxygenase (CMO) activity or signal peptide activity. The specification as filed provides sufficient guidance with regards to the isolation, characterization, and use of genes encoding proteins according to SEQ ID NO: 2, 4, 6, or 17 wherein said proteins have choline monooxygenase activity or signal peptide activity, wherein said genes have a sequence according to SEQ ID NO: 1, 3, 5, or 16 respectively. However, the specification as filed does not provide specific guidance with regards to any other genes that would encode a protein comprising one or more modifications to the protein sequences according to SEQ ID NO: 2, 4, 6, or 17 and still maintain either signal peptide activity or CMO activity. The specification as filed does not provide sufficient guidance and/or instruction that would unambiguously direct one of skill in the art to design a gene sequence that would produce a protein comprising any number of amino acid substitutions, deletions, or additions to the sequences according to SEQ ID NO: 2, 4, 6, or 17, wherein the desired functional activity is maintained.

The claimed sequences encompass all corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have an unspecified degree of identity (similarity, homology), and so forth. The specification provides insufficient written description to support the genus encompassed by the instant claims.

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With the exception of the sequences corresponding to SEQ ID NO: 1, 3, 5 and 16, the skilled artisan cannot envision the detailed chemical structure of the encompassed gene sequences according to the present invention, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Additionally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that: "...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only SEQ ID NO: 1, 3, 5 and 16, but not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph. The species specifically

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disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 2 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by

Rathinasabapathi et al.

The instant claims are directed to a choline monooxygenase (CMO) gene encoding a protein according to SEQ ID NO: 2, 4, or 6, and proteins which comprises the amino acid sequence shown in SEQ ID NO: 2, 4, or 6 having deletion, substitution or addition of one or several amino acids and which has choline monooxygenase activity.

Rathinasabapathi et al. disclose and characterize a (CMO) isolated from spinach leaves (*Spinacia oleracea*). Since the instant claims encompasses sequences according to SEQ ID NO: 2, 4, or 6 and those comprising deletions, substitutions, or addition of one or more amino acids to said sequences, the choline monooxygenase gene of the present invention essentially reads on any nucleotide sequence which encodes a protein which has (CMO) activity. The choline monooxygenase enzyme according to Figure 4 (page 3457) of Rathinasabapathi et al. anticipates applicant's claimed choline monooxygenase due to the significant number of protein sequences that are encompassed by the instant claims.

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Rathinasabapathi et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

6. Claims 2, 4-6, 8, 10-12, and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Nuccio et al.

Nuccio et al. describe the CMO isolated from spinach, and a recombinant expression cassette comprising said spinach CMO gene for expression in tobacco plants (page 489, Figure 2, (a)). Additionally, this reference describes transgenic tobacco plants expressing spinach CMO (page 489, Figure 2, (b-f)). These transgenic tobacco plants were exposed to salt stress conditions, however the glycine betaine levels in the transgenic plants were very low as observed in unstressed non-transgenic plants. This observation indicates that the CMO+ transgenic tobacco plants were able to resist the effects of an environment of high salinity (see Page 491, and Figure 6). Nuccio et al. also described the subsequent extraction of active choline monooxygenase enzyme after transgenic expression in tobacco (see Experimental Section: RNA, protein and enzyme analyses, page 494).

Nuccio et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

Allowable Subject Matter

7. Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claims 3 and 9 are free of the prior art searched.

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9. The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record does not teach or suggest the precise nucleotide sequences according to SEQ ID NO: 1, 3, and 5 which encode choline monooxygenase proteins isolated from *Chenopodium album* comprising an amino acid sequence according to SEQ ID NO: 2, 4, or 6, respectively. Furthermore, the prior art of record does not teach or suggest the precise nucleotide sequence according to SEQ ID NO:16 which encodes a signal peptide comprising an amino acid sequence according to SEQ ID NO: 17.

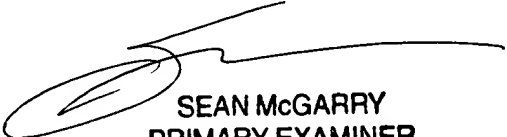
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps
Examiner
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JLE
November 30, 2001


SEAN McGARRY
PRIMARY EXAMINER